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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,551	02/14/2002	Matthew Lawrence Lynch	8422M	8636

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EXAMINER	
SADULA, JENNIFER R	
ART UNIT	PAPER NUMBER
1756	

DATE MAILED: 09/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/075,551	LYNCH ET AL.	
	Examiner	Art Unit	
	Jennifer R. Sadula	1756	

-- The MAILING DATE of this communication appears on th cover sh et with th correspondence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 February 2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2,4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed 2/14/2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The publications of Hyde and McCutcheon were not considered because the references were not received by the Examiner.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: 114 and 202 of figures 1 and 2 respectively. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: Page 4, line 28 of the spec- no reference is made to the lower range of "b", however a space exists where the reference

should be. The specification further does not define items "114" and "202" of figures 1 and 2 respectively. Appropriate correction is required.

On page 7, line 27, the word "tethers" as a complete sentence appears to be misplaced. On page 14 line 4 the second sentence begins, "The active can be...". It appears Applicants may have intended to state that "The active *ingredient* can be..." Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are in line 10 the claimed range for "b" is incomplete. Examiner notes that due to the fact that "b" is an "optional solvent" the limit for "b" has been examined in terms of $1.0>b\geq 0$. However, appropriate correction is still required.

Claim Rejections - 35 USC § 102

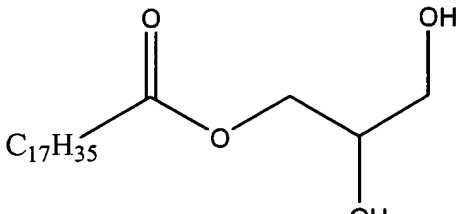
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

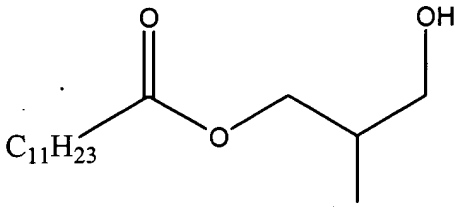
Claims 1-4, 11, 13-17 and 19-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Akashe et al., U.S. Patent No. 6,274,574 ("Akashe").

Applicants claim 1 is drawn toward an amphiphile capable of forming a cubic liquid crystalline (LC) phase and an additive of either an anchor, tether, or combination thereof and satisfying particular mass fractional requirements. In claims 1 and 17 an additional solvent is optional. In Applicants' claims 14 and 16 the solvent is a requisite. Specifically, claim 1 is drawn toward a cubic LC precursor; claim 14 to a bulk cubic LC gel; claim 16 to a dispersion of cubic LC particles and claim 17 is drawn toward a method of preparing the precursor of claim 1. The amphiphile of claim 1 is specified in claim 2 to be a monoglyceride of a specified formula

Akashe teaches use of mesophase-stabilized compositions for delivery of cholesterol-reducing sterols and stanols in food products wherein the compositions contain plant sterols and/or plant esters and a mixture of two or three different emulsifiers (abstract; 5:11-14). Component B of Akashe may be a monoglyceride of the following formulas (10:63-67):



glycerol monostearate



glycerol monolaurate

both of which satisfy Applicants' requirements of the amphiphilic component being a cubic liquid crystalline precursory monoglyceride of the formula shown in Applicants' claim 2. With regard to the specification of an anchor, tether, or combination thereof, an "emulsifier" by definition is a surface-active agent or "surfactant" (Hawley's Condensed Chemical Dictionary, 14th ed.). Examiner notes that assorted surfactants, which are specified in Applicants' claim 4, are listed by Applicants as anchors, thereby satisfying the requirement. Examiner further notes that the difference with regard to a tether and an anchor as defined by the Applicants in merely in the size of the compound. Thus the Examiner interprets Akashe as teaching both anchors and tethers as the sizes of the materials of Akashe vary.

Component B of Akashe is formulated as either A, B, and C (herein composition 1) and as B and C (herein composition 2). With regard to Applicants' claims 3 and 14, these compositions when mixed with water form cubic mesophases and may form as a gel depending upon the solvent level (9:20-46). The ranges of components fall within Applicants' specified ratios (13:53-14:28).

Claims 11 and 15 are drawn toward an active ingredient being added to the composition. Applicants define "active ingredient" as agrochemicals, pharmaceutical, cosmetic, enzyme, etc (pages 14-15 of Applicants' specification). Examiner notes that *anything* really can be

interpreted as an "active ingredient" as really there are few compounds which will never fall within these categories. However, Akashe teaches that a cholesterol-reducing compound is added to the oil phase containing A and B (14:36). Cholesterol reduction is considered both cosmetic and health-conscious/medical. Further, the compounds are indeed carriers of food which is the supplementation of nutrients.

Akashe further teaches the compounds for use in food products to make the materials taste and texture more palatable. This is determined to anticipate the limitation of "nutrient delivery" as specified by Applicants' claim 13.

Lastly, these materials are combined a variety of ways. With regard to Applicants' claim 17, Akashe teaches powdered forms of A and B to be dispersed in an oil phase at room temperature and then heated to about 80°C-100°C (14:29-36). With regard to Applicants' claim 19, components A and B may be in powdered form wherein the coarse emulsion is homogenized via a moderate to high shear device (14:29-47). The stimulus for forming the cubic liquid crystalline dispersion is either the addition of materials, such as the amphiphile or solvent, the subjection of high shear, or either heating or cooling (6:38-7:7).

Claims 1-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Anderson, U.S. Patent No. 6,482,517.

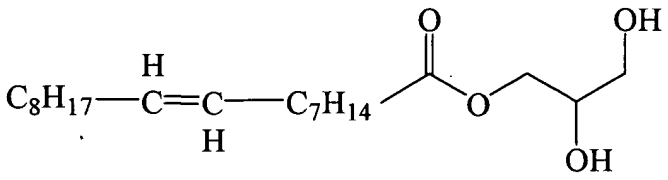
Anderson teaches coated particles and methods of making such wherein the particle is coated with a nonlamellar crystalline material including an internal matrix core having at least one nanostructured liquid phase for use as a delivery mechanism of active agents such as pharmaceuticals, nutrients, pesticides and the like (abstract). With regard to Applicants' claim 3,

column 6 of Anderson teaches all related polar solvents and moieties, as well as a variety of amphiphiles including surfactants, butanol, and lipids. Preferably Anderson teaches the use of any amphiphile that at very low concentrations lowers interfacial tensions between a polar solvent (such as water) and any hydrophobe (7:54-61). Anderson further teaches, as is discussed in claim 5, that the nonostructured liquid phase comprises a polar solvent, an amphiphile and a surfactant or lipid.

Examiner notes that the surfactant or lipid as taught acts as either an anchor or tether as claimed by Applicants. The surfactants of Anderson anticipate Applicants' claims 4-10 wherein, as Anderson begins in column 9, the surfactants useful in the formation of nonostructured liquid crystalline phases include anionics (negatively charged), cationics (positively charged), zwitterionics (both positively and negatively charged) and semipolar surfactants. Each of these subheadings includes both anchors and tethers as claimed by the Applicants wherein the surfactants are plant derived or surfactants of biological origin (7:54-61), however Anderson specifically recites the use of block copolymers as tethers (25:54) Furthermore, polybutadien is well known to yield nanostructured liquid crystals (9:55-58) thereby specifically satisfying claims 7 and 9. With regard to claim 8, Anderson teaches preferred surfactants which are FDA-approved as injectables include chitin and cellulose derivatives (26:46-27:36).

With regard to claim 2, Anderson teaches that the preferred amphiphiles include glycerides, aromatic chains, long chain alcohols, aliphatics, low molecular weight hydrophobic polymers and acylated sorbitans (27:37-50). Further, Anderson teaches that the reversed bicontinuous cubic phase does appear in a number of binary systems with single-tailed surfactants, such as those of many monoglycerides (include glycerol monooleate), and a number

of nonionic PEG-based surfactants with low HLB (23:22-32). Glycerol monooleate (also known as "monoolein") has the general structure:



Therefore, in accordance with Applicants' expressed monoglyceride, R is C_{17} and is not halogenated. However, it should be noted that additional monoglycerides are anticipated by Anderson. Lastly, it is noted that Anderson teaches the Applicants' expressed mass fractions in the examples.

Claims 1-4, 7-8, 11-18 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Engström et al., U.S. Patent No. 5,371,109 ("Engström")

Engström teaches a controlled release composition for a biologically active material dispersed in a cubic liquid crystalline phase comprising at least one monoglyceride of an unsaturated fatty acid; at least one triglyceride (acting as either an anchor or tether) and at least one polar liquid such as water (abstract). The invention of Engström further relates to the encapsulation of a biologically active material, herein known as an "active ingredient" (abstract).

With regard to Applicants' claim 2, Engström teaches the preferred monoglyceride to be monoolein or monolinolein (3:8-10). As noted above, monoolein satisfies the applicants' claimed structure. The ratio of components of Engström is satisfactorily taught (3:33-45), wherein, when the active ingredient is added the active material is present in an amount of 0.1 to

10% by weight although the invention of Engström is not limited to this specific concentration (4:14-17).

The triglycerides of Engström which act as anchors or tethers, depending on the size of the structure, is an unsaturated fatty acid having 16-22 carbon atoms however the triglyceride may be contained in a compositional precursor (3:11-20). Thus, claims 4, 7 and 8 are satisfied.

With regard to claims 17-20, Engström teaches the generic methods as claimed wherein a stimulus is addition dropwise of a solution of active ingredient in order to preserve the structure of the active ingredient (such as is the case when utilizing proteins) (4:32-68). Another stimulus taught by Engström is merely mixing of the components (5:10-15). Lastly, with regard to Applicants' claim 18, the materials are taught to be aqueous or in liquid form (see examples of Engström).

With regard to Applicants' claim that the material form a gel, Examiner notes that the definition of a "gel" is merely a colloidal formation. A polymer dispersed liquid crystal (PDLC) in any way, shape, or form satisfies this definition. Thus the Examiner notes that the dispersion of cubic liquid crystals of Engström satisfies this requirement.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Larsson et al., European Patent No. 0 429 419 teaches an implant material composition comprising an active component of tissue substitute (active ingredient) distributed in a mixture of a water-based liquid (solvent), a monoglyceride (amphiphile) and optionally a triglyceride

wherein the mixture is capable of forming into a cubic LC phase when contacted with an aqueous liquid (abstract). The monglyceride may be a single monglyceride or a mixture thereof and is generally of an unsaturated fatty acid (6:19-29), wherein especially preferable is the use of monoolein which satisfies Applicants' structure of claim 2. No tether or anchor appears to be taught as triglycerides appear to not fall within Applicants' definition of an anchor or tether. The same holds true for Larsson et al., U.S. Patent No 5,196,201.

The following references all teach monoolein in conjunction with a polar solvent and anchors or tethers for use in forming cubic liquid crystals and drug delivery polymers:

1. Engström et al., "A Study of Polar Lipid Drug Carrier Systems Undergoing a Thermoreversible Lamellar-to-Cubic Phase Transition"

2. Biatry, U.S. Patent No. 6,506,391

3. Engström et al., "Phase Behaviour of the Lidocaine-Monoolein-Water System"

4. Alfons et al., "Drug Compatibility with the Sponge Phases Formed in Monoolein, Water and Propylene Glycol or Poly(ethylene glycol)"

5. Larsson et al., U.S. Patent No 5,196,201

6. Hansen et al., U.S. Patent No 6,228,383

7. Fontell, "Cubic Phases in Surfactant and Surfactant-like Lipid Systems"

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer R. Sadula whose telephone number is 703.305.4835. The examiner can normally be reached on Monday through Friday, 10am-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark F. Huff can be reached on 703.308.2464. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0661.

MARK F. HUFF
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700

JRS
15 September 2003